ASX Release

Successful Completion of Phase 1b Breast Cancer Trial – Phase 2 Being Initiated

- Expansion cohort of Phase 1 trial in locally advanced and metastatic breast cancer completed
- Pre-specified safety criteria met for advancing to Phase 2
- Complete pathologic response observed in ER+ locally advanced breast cancer

Melbourne, Australia (6 April 2017): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX) is pleased to announce that the pre-specified success criteria of its Phase 1b breast cancer trial have been met, and the study will now progress to Phase 2.

The Phase 1b trial evaluated PTX-200 in combination with paclitaxel in women with HER2-negative breast cancer, including ER-/PR- (triple negative) and ER+ breast cancer[1]. The trial was conducted at the Montefiore Medical Center, Albert Einstein College of Medicine in New York (Montefiore Cancer Center) and the H. Lee Moffitt Cancer Center in Tampa (Moffitt).

The Phase 1b study comprised a dose escalation cohort, followed by an expansion cohort.

The dose escalation cohort enrolled 17 patients to determine the recommended Phase 2 dose (RPTD) for the efficacy study. The RPTD was determined to be 35 mg/m^2 of PTX-200, together with 80mg/m^2/week of paclitaxel. The study population included patients with metastatic breast cancer and other cancers.

The expansion cohort comprised 12 patients with Stage IIB-IV HER2-negative breast cancer. Patients received the RPTD of PTX-200 plus paclitaxel, followed by standard doxorubicin-cyclophosphamide and surgery for stage IIB-IIIC disease.

The pre-specified expansion cohort success criteria was achieved and the study will now continue onto the Phase 2 trial in locally advanced breast cancer.

In the Phase 1b Preliminary Efficacy Analysis of the expansion cohort, eight patients to date have been evaluated for clinical response. Of these eight patients, one had a complete response; four had partial responses; two exhibited stable disease; and one had progressive disease.

Five of the 12 patients enrolled in the expansion cohort had stage IIB-IIIC disease (locally advanced breast cancer), and their responses will be included in the Phase 2 study analysis.

[1] Triple negative breast cancer is a type of breast cancer that does not have any of the three receptors commonly found on breast cancer cells: estrogen, progesterone and HER2 receptors. ER+ breast cancer does have estrogen receptors. The treatment of triple negative and ER+/HER2 negative breast cancers is characterized by a high level of unmet clinical need (GlobalData 2016).

Of these five patients, three patients so far have gone on to surgery, with one patient with stage IIIB ER+ breast cancer exhibiting a pathologic complete response[2].

The study's Principal Investigator, Professor Joseph Sparano, MD of Montefiore Cancer Center, said "Only about 15% of patients with ER+, HER2-negative breast cancer achieve a pathologic response to neoadjuvant chemotherapy – we are therefore very encouraged to see that one of the two patients with ER+ disease treated thus far have had a pathologic response. This provides an encouraging signal as we initiate the Phase 2 trial."

Prescient Therapeutics' CEO, Steven Yatomi-Clarke said "This is an important clinical milestone for the Company. We are very pleased with the results from the Phase 1b study and are cautiously confident that the early signals of activity of PTX-200 will continue into the Phase 2 study.

It is also pleasing that the Phase 2 study is off to a rolling start, with five patients from our Phase 1b expansion cohort qualifying for analysis in Phase 2.

With our other trials in AML and ovarian cancer also underway, this is a very exciting time for the Company."

ENDS

About Prescient Therapeutics Limited (PTX)

PTX is a clinical stage oncology company developing novel compounds that show promise as potential new therapies to treat a range of cancers that have become resistant to front line chemotherapy.

PTX's lead drug candidate PTX-200 inhibits an important tumor survival pathway known as Akt, which plays a key role in the development of many cancers, including breast and ovarian cancer, as well as leukemia. Unlike other drug candidates that target Akt inhibition which are non-specific kinase inhibitors that have toxicity problems, PTX-200 has a novel mechanism of action that specifically inhibits Akt whilst being comparatively safer. This highly promising compound is now the focus of three current clinical trials. The first is a Phase 1b/2 trial evaluating PTX-200 as a new therapy for relapse and refractory Acute Myeloid Leukemia, being conducted at Florida's H. Lee Moffitt Cancer Center (Moffitt) and Yale Cancer Center in New Haven, Connecticut (Yale) under the leadership of Professor Jeffrey Lancet, MD.

PTX is also conducting a Phase 2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York and the Moffitt. The third trial is a Phase 1b/2 trial of PTX-200 in combination with current standard of care is also underway in patients with recurrent or persistent platinum resistant ovarian cancer at the Moffitt.

PTX's second novel drug candidate, PTX-100, is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase (GGT). It also blocks the Ral and Rho circuits in cancer cells which act as key oncogenic survival pathways, leading to apoptosis (death) of cancer cells. PTX-100 was well tolerated and achieved stable disease in a Phase I trial in advanced solid tumors.

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[2] Pathologic complete response means disappearance of disease upon microscopic assessment.